REMARKS

The Office Action of October 10, 2007, has been received and reviewed. Claims 1-16 are currently pending in the application. Claims 6-8 were previously withdrawn from consideration. Claims 1-5 and 9-16 are under consideration. Claims 1-5 and 9-16 stand rejected. The claims are to be amended as previously set forth. All amendments are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 103(a)

Claims 1-15 and 9-16 stand rejected under 35 U.S.C. § 103(a) as assertedly being obvious over Taylor *et al.* (J. Vir., Apr. 1990, Vol. 64, No. 4, pgs. 1441-1450) (hereinafter "Taylor"). Applicants respectfully traverse the rejections as hereinafter set forth.

To establish a *prima facie* case of obviousness, the prior art itself or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention are to have taught or suggested the claim elements. Additionally, the Examiner must determine whether there is "an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Further, rejections on obviousness grounds "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id* at 1741, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). "Often, it will be necessary for a [fact finder] to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed . . . . To facilitate review, this analysis should be made explicit." *Id.* Furthermore, to establish a *prima facie* case of obviousness there must have been a reasonable expectation of success. M.P.E.P. § 2143.02. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742.

Applicants respectfully submit that Taylor in combination with the ordinary skill in the art does not teach or suggest each of the claim elements or otherwise render the claimed subject

matter obvious.

Applicants note that where Taylor innoculates animals, it is with an isolated recombinant protein vaccine. Taylor at 1442-1443 and 1446. In contrast, claim 1 is directed, in part, to the use of a vaccine comprising an infectious copy of an avian-paramyxovirus (the "second vaccine" of claim 1). Applicants respectfully note that Taylor, combined with the ordinary skill in the art, does not teach or suggest using infectious clones as outlined in claim 1 and thus cannot make obvious the method of claim 1. Moreover, applicants wish to emphasize that that the present inventors were, for the first time, able to generate a recombinant infectious copy of NDV. The generation of such an infectious clone was only possible through the inventors identification of the 5'-terminal end of the genome. Thus, prior to the present application, one of ordinary skill in the art would have been unable to generate infectious clones of NDV that are a prerequisite for the method of claim 1.

Furthermore, claim 1 recites providing a population of animals wherein one or more of the animals in the population have been vaccinated with the second vaccine. As noted previously, the vaccine of Taylor does not fit the criteria of the "second vaccine" of claim 1 as the vaccine of Taylor is a peptide vaccine and not an infectious clone (which, prior to the present application, could not have been generated). Thus Taylor, combined with the ordinary skill in the art, does not teach or suggest providing a population with at least one animal inoculated with the second vaccine of claim 1.

Also, the teaching of Taylor is inefficient for use as a vaccine. As is stated in paragraph 45, on page 9 of the Specification, the onset of protection against Newcastle disease following vaccination with recombinant vaccines that express the NDV F proteins is severely delayed compared to that following vaccination with a conventional NDV vaccine, or an NDV-based vaccine comprising one or more modified proteins. Thus, one of ordinary skill in the art would not have been motivated to vaccinate a population of animals with the vaccine of Taylor, as opposed to more conventional vaccines, since the onset of protection is delayed in animals typically sacrificed at a young age (*See*, Taylor at 1441, column 1, noting that vaccination is complicated by the fact that broilers live to be only 6 to 8 weeks of age).

Further, applicants respectfully note that Taylor does not teach a method of detecting NDV F protein in samples from chickens that were vaccinated with lentogenic or mesogenic

strains of NDV, or from chickens that were vaccinated with wild-type NDV as suggested by the Examiner. Taylor only teaches the detection of an NVD F fusion protein, where the NVD F protein is isolated from a velogenic virus.

Moreover, the applicants respectfully submit that the Office Action mistakenly asserts that Taylor teaches that a comparison of sequence differences in the F-protein can differentiate between wild-type NDV and unmodified vaccine strains. A comparison of the F-proteins from a velogenic NDV strain (Texas) with another velogenic strain (Texas GB) and a mesogenic Beaudette C strain is provided in FIG. 4 of Taylor. Applicants note that all of the changes in respect of the velogenic Texas strain that occur relative to the mesogenic Beaudette C strain also occur in the velogenic Texas GB strain. This result suggests that the observed differences are not related to variance in virulence characteristics. Taylor at 1448, column 1, lines 18-24. Thus, the differences observed by Taylor are NOT sufficient to discriminate between wild-type NDV and unmodified vaccine strains, clearly obviating the need for a method to discriminate between infected and vaccinated animals. Thus, one of ordinary skill in the art would not have been motivated to modify, if it were even possible, the teachings of Taylor to arrive at the method of claim 1.

Finally, claim 1 relates to sorting into different populations based on a negative inference. Even if the vaccine of Taylor were considered to correspond to the second vaccine of claim 1 (which it does not as noted *supra*), Taylor then must correlate inoculation with the vaccine by the detection of antibodies generated specifically to that vaccine. Applicants note that specific detection of the vaccine of Taylor, separate from wild-type infection, may only be accomplished by using a fusion protein having no modification to the base sequence of the NDV F protein (which is all that Taylor discloses). Thus, the only way to differentiate between animals vaccinated by Taylor from those of wild-type infections is through the presence of antibodies specific, at least in part, to those sections fused to NDV F, which are not present in wild-type strains. In contrast, the method of claim 1 directs that an animal be placed in category "(b)" (including those animals vaccinated with the second vaccine of claim 1) only if there is an antibody elicited by the first vaccine that would not be elicited by the second vaccine.

Applicants note that any detection scheme of Taylor to differentiate wild-type virus (detecting antibodies against the portion fused to NDV F) is inoperable with the classification

scheme outlined in the method of claim 1. Specifically, the method of claim 1 classifies based on the presence of antibodies that would be generated by wild-type virus or unmodified vaccines that would not be generated by the second vaccine of claim 1. If the vaccine of Taylor were used in such a classification scheme, all the animals would be classified in group "(a)" since the vaccine of Taylor contains a wild-type sequence of NDV F. Thus, if the vaccine of Taylor were applied, no classification based on the presence of antibodies to wild-type NDV F would be possible using the scheme of claim 1.

For at least the foregoing reasons, applicants respectfully request the withdrawal of the rejection of claim 1 under 35 U.S.C. § 103 and reconsideration of same.

In addition, applicants respectfully submit that claims 2-5 and 9-16 are not obvious, *inter alia*, as they each depend, directly or indirectly, from non-obvious claim 1. As such, applicants respectfully request the withdrawal of the rejections of claims 2-5 and 9-16 and reconsideration of same.

CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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